

**CERTIFICATION OF COMPLIANCE AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ST. FRANCIS HOSPITAL AND MEDICAL CENTER  
AND  
ST. FRANCIS CARE MEDICAL GROUP, P.C.**

**I. PREAMBLE**

St. Francis Hospital and Medical Center and St. Francis Care Medical Group, P.C. (collectively "St. Francis") hereby enter into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). Contemporaneously with this CCA, St. Francis is entering into a Settlement Agreement with the United States and the State of Connecticut, and this CCA is incorporated by reference into the Settlement Agreement.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

**II. INTEGRITY REQUIREMENTS**

St. Francis shall, for a period of three years from the Effective Date of this CCA:

A. Continued Implementation of Compliance Program. St. Francis shall continue to implement a Compliance Program, which is jointly administered by St. Francis Hospital and Medical Center and St. Francis Care Medical Group, P.C. and is described in the attached Declaration (incorporated by reference as Appendix A). St. Francis shall continue to provide, at a minimum, the same level of resources currently provided, throughout this time period. St. Francis may amend its Compliance Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

B. Management and Accountability of Vaccines. This Section II.B of the CCA pertains specifically to Vaccines received free of charge from the Vaccines for Children Program (hereinafter referred to as "Vaccines"). Within 90 days following the Effective Date of this CCA, St. Francis shall assess its internal procedures relating to the use and financial disposition of any Vaccines. If necessary, St. Francis shall establish and implement, or revise, internal procedures so they are reasonably designed to track the

receipt, storage, inventory, use and financial disposition of Vaccines, and to prevent the billing of Vaccines to patients, Federal health care programs, or third party insurers.

As part of each Annual Report, St. Francis shall describe the general procedures used to track the receipt, storage, use, inventory, and financial disposition of Vaccines. In addition, St. Francis shall report the following information:

1. the aggregate number of Vaccines received during the Reporting Period;
2. the entity or individual that provided each type of Vaccine to St. Francis;
3. the specific manner in which each Vaccine was used. For example, if St. Francis used the Vaccine to treat patients, St. Francis shall list the name of each patient, the source of the patient's insurance (if any), the number of Vaccines used to treat each patient, the date(s) of such use, and the manner in which the patient or any insurer was charged (if at all) for the sample. If the Vaccines were used to replace a damaged or expired product, St. Francis shall provide the number of Vaccines used in this manner, the date of the replacement, and the number of units of product, if any, returned to the manufacturer. If the Vaccines were used for training purposes, St. Francis shall identify to whom the training was provided, the date(s) on which the training was provided, and how many Vaccines were used in providing such training. If St. Francis uses the Vaccines in any other manner, it shall describe, in detail, the manner in which those Vaccines were used; and
4. a certification by the Compliance Officer that St. Francis has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

In the event the OIG has reason to believe that: (a) St. Francis's management and accountability of Vaccines, including the billing and payment of Vaccines, fails to conform to the requirements of this Agreement; or (b) the Vaccine information reported in accordance with this Section II.B. is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether St. Francis's management and accountability of Vaccines complies with the requirements of the Agreement and/or the Vaccine information reported pursuant to Section II.B. is accurate ("Validation Review"). St. Francis agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify St. Francis of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary.

To resolve any concerns raised by the OIG, St. Francis may request a meeting with the OIG to discuss the underlying issues about St. Francis's compliance with the requirements of this CIA; present any additional or relevant information; and/or propose alternatives to the proposed Validation Review. St. Francis agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Vaccine issues with St. Francis prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

C. Reporting of Overpayments. St. Francis shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money St. Francis has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, St. Francis identifies or learns of any Overpayment, St. Francis shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, St. Francis shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, St. Francis shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

D. Reportable Events. St. Francis shall report to OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, or (2) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. In such report, St. Francis shall include the following information:

1. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in

Section II.C, and shall include all of the information on the Overpayment Refund Form, as well as:

- a. the payor's name, address, and contact person to whom the Overpayment was sent; and
  - b. the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;
2. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
  3. a description of St. Francis's actions taken to correct the Reportable Event; and
  4. any further steps St. Francis plans to take to address the Reportable Event and prevent it from recurring.

E. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery, St. Francis shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to St. Francis conducted or brought by a governmental entity or its agents involving an allegation that St. Francis has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. St. Francis shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

F. Annual Reporting Requirements. St. Francis shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):

1. A description of any material amendments to its Compliance Program and the reasons for such changes;
2. Any changes to the level of resources dedicated to its Compliance Program and the reasons for such changes;
3. A summary of all internal or external reviews, audits, or analyses of its Compliance Program (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or

analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

4. A summary of all internal or external reviews, audits, or analyses related to the management and accountability of vaccines (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

5. A report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report; and

6. A certification by the Compliance Officer that: (a) to the best of his or her knowledge, except as otherwise described in the Annual Report, St. Francis is in compliance with the requirements of this Section II; and (b) he or she has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

St. Francis Hospital and Medical Center and St. Francis Care Medical Group, P.C. shall submit a joint Annual Report for each Reporting Period, as St. Francis Hospital and Medical Center and St. Francis Care Medical Group, P.C. jointly administer the same Compliance Program. The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

G. Notifications and Submission of Annual Reports. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202-619-2078  
Facsimile: 202-205-0604

St. Francis:

Jennifer Schneider  
Corporate Compliance Officer  
St. Francis Hospital and Medical Center  
114 Woodland Street  
Hartford, CT 06105  
Telephone: 860-714-5360  
Facsimile: 860-714-8161

Unless otherwise specified, all notifications and reports required by this CCA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such report or notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

H. OIG Inspection, Audit, and Review Rights. In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of St. Francis's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of St. Francis's locations for the purpose of verifying and evaluating: (a) St. Francis's compliance with the terms of this CCA; and (b) St. Francis's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by St. Francis to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of St. Francis's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. St. Francis shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. St. Francis's employees may elect to be interviewed

with or without a representative of St. Francis present. Nothing in this CCA or any communication or report made pursuant to this CCA shall constitute or be construed as a waiver by St. Francis of St. Francis' attorney-client, work product, or other applicable and appropriately asserted privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by St. Francis to avoid its obligations to comply with the provisions of this CCA.

I. Document and Record Retention. St. Francis shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law).

### **III. BREACH AND DEFAULT PROVISIONS**

St. Francis is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, St. Francis and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day St. Francis fails to establish and implement any of the following compliance program elements as described in Section II and the Declaration attached to this CCA as Appendix A:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the annual training of owners, officers, directors, employees, medical staff members, and any other persons who provide patient care items or services or who perform billing or coding functions on behalf of St. Francis (including but not limited to contractors, subcontractors, and agents of St. Francis);

f. an internal audit program that includes periodic reviews to monitor St. Francis's compliance with Federal health care program requirements;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements; and

i. notification of government investigations and legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day St. Francis fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.F by the stated deadlines for submission.

3. A Stipulated Penalty of \$1,500 for each day St. Francis fails to grant access to the information or documentation as required in Section II.H of this CCA. (This Stipulated Penalty shall begin to accrue on the date St. Francis fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of St. Francis as part of its Annual Reports or otherwise required by this CCA.

5. A Stipulated Penalty of \$1,000 for each day St. Francis fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to St. Francis, stating the specific grounds for its determination that St. Francis has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps St. Francis shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 days after St. Francis receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section III.A.

B. Timely Written Requests for Extensions. St. Francis may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CCA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after St. Francis fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after



St. Francis receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that St. Francis has failed to comply with any of the obligations described in Section III.A and after determining that Stipulated Penalties are appropriate, OIG shall notify St. Francis of: (a) St. Francis's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, St. Francis shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section III.E. In the event St. Francis elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until St. Francis cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CCA and shall be grounds for exclusion under Section III.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section II.G.

4. *Independence from Material Breach Determination.* Except as set forth in Section III.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that St. Francis has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section III.D below.

D. Exclusion for Material Breach of this CCA.

1. *Definition of Material Breach.* A material breach of this CCA means:

- a. a failure by St. Francis to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section II.C;

b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section III.A; or

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section III.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CCA by St. Francis constitutes an independent basis for St. Francis's exclusion from participation in the Federal health care programs. Upon a determination by OIG that St. Francis has materially breached this CCA and that exclusion is the appropriate remedy, OIG shall notify St. Francis of: (a) St. Francis's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* St. Francis shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. St. Francis is in compliance with the requirements of the CCA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) St. Francis has begun to take action to cure the material breach; (ii) St. Francis is pursuing such action with due diligence; and (iii) St. Francis has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, St. Francis fails to satisfy the requirements of Section III.D.3, OIG may exclude St. Francis from participation in the Federal health care programs. OIG shall notify St. Francis in writing of its determination to exclude St. Francis (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 days after the date of St. Francis's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, St. Francis may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution.

1. *Review Rights.* Upon OIG's delivery to St. Francis of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, St. Francis shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. §1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether St. Francis was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. St. Francis shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CCA and orders St. Francis to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless St. Francis requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CCA shall be:

- a. whether St. Francis was in material breach of this CCA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) St. Francis had begun to take action to cure the material breach within that period; (ii) St. Francis has pursued and is pursuing such action with due diligence; and (iii) St. Francis provided to OIG within that period a reasonable timetable for curing the material breach and St. Francis has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for St. Francis, only after a DAB decision in favor of OIG. St. Francis's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude St. Francis upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that St. Francis may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. St. Francis shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of St. Francis, St. Francis shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

#### **IV. EFFECTIVE AND BINDING AGREEMENT**

St. Francis and OIG agree as follows:

A. This CCA shall be binding on the successors, assigns, and transferees of the parties;

B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;

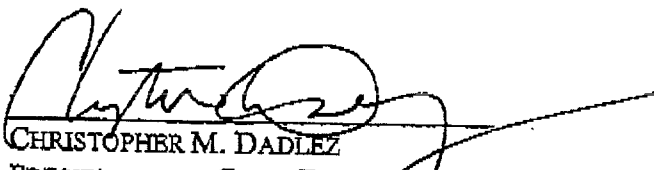
C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;

D. OIG may agree to a suspension of St. Francis's obligations under this CCA in the event of St. Francis's cessation of participation in Federal health care programs. If St. Francis withdraws from participation in Federal health care programs and is relieved of

its CCA obligations by OIG, St. Francis shall notify OIG at least 30 days in advance of St. Francis's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CCA should be reactivated or modified.

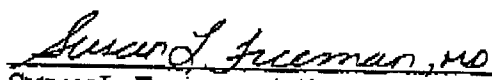
E. The undersigned St. Francis signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

ON BEHALF OF ST. FRANCIS HOSPITAL AND MEDICAL CENTER

  
CHRISTOPHER M. DADLEZ  
PRESIDENT AND CHIEF EXECUTIVE OFFICER  
ST. FRANCIS HOSPITAL AND MEDICAL CENTER

2/01/05  
DATE

ON BEHALF OF ST. FRANCIS CARE MEDICAL GROUP, P.C.

  
SUSAN L. FREEMAN, M.D.  
PRESIDENT  
ST. FRANCIS MEDICAL GROUP, P.C.

2/1/05  
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

\_\_\_\_\_  
LEWIS MORRIS  
Chief Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

\_\_\_\_\_  
DATE

**ON BEHALF OF ST. FRANCIS HOSPITAL AND MEDICAL CENTER**

\_\_\_\_\_  
CHRISTOPHER M. DADLEZ  
PRESIDENT AND CHIEF EXECUTIVE OFFICER  
ST. FRANCIS HOSPITAL AND MEDICAL CENTER


\_\_\_\_\_  
DATE


**ON BEHALF OF ST. FRANCIS CARE MEDICAL GROUP, P.C.**

\_\_\_\_\_  
SUSAN L. FREEMAN, M.D.  
PRESIDENT  
ST. FRANCIS MEDICAL GROUP, P.C.

\_\_\_\_\_  
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

  
\_\_\_\_\_  
LEWIS MORRIS  
Chief Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

  
\_\_\_\_\_  
DATE

## DECLARATION

The declarants are currently the President and Chief Executive Officer for St. Francis Hospital and Medical Center and the President of St. Francis Care Medical Group, P.C., respectively, and have personal knowledge of the facts stated herein. The following describes the compliance program (Program) currently in place and jointly administered at St. Francis Hospital and Medical Center and St. Francis Care Medical Group, P.C. (collectively “St. Francis”).

1. The annual budget for the Program is attached hereto as Exhibit 1 and St. Francis shall sustain, at a minimum, the levels of funding reflected therein for three years subsequent to the Effective Date.

2. The Program includes a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. The Compliance Officer also is responsible for monitoring the day-to-day compliance activities of St. Francis. The Compliance Officer is a member of senior management of St. Francis and is not subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer makes periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of St. Francis and is authorized to report on such matters to the Board of Directors at any time.

3. The Program includes a Compliance Committee that is chaired by the Compliance Officer and that is made up of other members of senior management necessary to support the Compliance Officer in fulfilling his/her responsibilities under the Program (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations).

4. St. Francis has in place a Code of Conduct that includes: (a) St. Francis’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements; (b) St. Francis’s requirement that all of its personnel are expected to comply with all Federal health care program requirements and with the Policies and Procedures described in Paragraph 5 below; (c) the requirement that all of St. Francis’s personnel are expected to report to the Compliance Officer or other appropriate individual designated by St. Francis suspected violations of any Federal health care program requirements or of St. Francis’s own Policies and Procedures; (d) the possible consequences to both St. Francis and its personnel of failure to comply with Federal health care program requirements and with St. Francis’s own Policies and Procedures and the failure to report such noncompliance; and (e) the right of St. Francis’s personnel to use the Disclosure Program described in Paragraph 8 below and St. Francis’s commitment



to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures. Each owner, officer, director, employee, medical staff member, and any other person who provide patient care items or services or who perform billing or coding functions on behalf of St. Francis (including but not limited to contractors, subcontractors, and agents of St. Francis) is required to certify in writing that he or she has received, read, understood, and will abide by the Code of Conduct.

5. St. Francis has in place Policies and Procedures regarding the operation of the Program and St. Francis's compliance with Federal health care program requirements, including the management and accountability of vaccines under the Vaccines for Children Program. The Policies and Procedures are made available to all relevant St. Francis personnel. At least annually (and more frequently, if appropriate), St. Francis reviews and updates as necessary its Policies and Procedures and, if revisions are made, makes available the relevant portions of any revised Policies and Procedures to all St. Francis personnel whose job functions relate to the revised Policies and Procedures.

6. St. Francis has in place an annual training program that requires all owners, officers, directors, employees, medical staff members, and any other persons who provide patient care items or services or who perform billing or coding functions on behalf of St. Francis (including but not limited to contractors, subcontractors, and agents of St. Francis) to attend at least one hour of annual compliance training that addresses St. Francis's Code of Conduct and the operation of the Program. St. Francis's annual training program also requires additional hours of training for all employees and any other persons who provide patient care items or services or who perform billing, coding, or claims submission functions on behalf of St. Francis (including but not limited to contractors, subcontractors, agents of St. Francis). Such additional training addresses: (a) the Federal health care program requirements regarding the accurate coding and submission of claims; (b) policies, procedures, and other requirements applicable to the documentation of medical records; (c) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (d) applicable reimbursement statutes, regulations, and program requirements and directives; (e) the legal sanctions for violations of Federal health care program requirements; (f) examples of proper and improper claims submission practices; and (g) the management and accountability of vaccines under the Vaccines for Children Program. St. Francis maintains written or electronic records that identify the type of annual training provided, the date(s) of the training, and the attendees. Persons providing the training are knowledgeable about the subject area. St. Francis reviews the training content on an annual basis and, as appropriate, updates the training to reflect changes in Federal health care program requirements and/or any issues discovered during the internal audits described in Paragraph 7 below.

7. St. Francis has in place an internal audit program that includes periodic reviews to monitor St. Francis's compliance with Federal health care program requirements, including focused reviews relating to specific risk areas identified by the OIG and/or through the Program. In particular, St. Francis's Internal Audit Department conducts semi-annual audits of immunization charges in order to assure compliance with the Vaccines for Children Program. As part of the internal audit program, St. Francis has the equivalent of 3.05 full-time qualified employees who are assigned to review St. Francis's compliance with Federal health care program requirements.

8. St. Francis maintains a Disclosure Program that includes a mechanism to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with St. Francis's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. St. Francis publicizes the existence of the disclosure mechanism to all personnel.

The Disclosure Program emphasizes a nonretribution, nonretaliation policy and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Each disclosure is reviewed by the Compliance Officer, who either investigates the disclosure or refers the disclosure to the relevant department or manager for follow up and any appropriate corrective action.

The Compliance Officer (or designee) maintains a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of St. Francis's internal review of the allegations, and any corrective action taken in response to the internal review.

9. St. Francis has in place a policy and procedure for screening all prospective owners, officers, directors, employees, contractors, agents, and medical staff members to ensure that they are not Ineligible Persons<sup>1</sup> by: (a) requiring such persons to disclose whether they are an Ineligible Person; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists shall

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<sup>1</sup> An "Ineligible Person" is an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

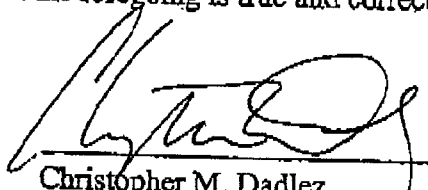
hereinafter be referred to as the "Exclusion Lists"). St. Francis also performs annual screening of its current owners, officers, directors, employees, contractors, agents, and medical staff members against the Exclusion Lists and requires all owners, officers, directors, employees, contractors, agents, and medical staff members to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

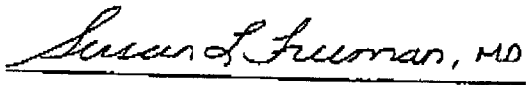
St. Francis also has a policy in place that, if St. Francis has actual notice that an owner, officer, director, employee, contractor, agent, or medical staff member has become an Ineligible Person, St. Francis will remove such person from responsibility for, or involvement with, St. Francis's business operations related to the Federal health care programs and will remove such person from any position for which the person's compensation or items or services furnished, ordered, or prescribed by the person are paid in whole or in part, directly or indirectly, by Federal health care programs or otherwise with Federal funds, at least until such time as the person is reinstated into participation in the Federal health care programs. (Nothing in this Declaration affects the responsibility of St. Francis to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded individuals or St. Francis's liability for overpayments received by St. Francis as a result of billing any Federal health care program for such items or services.).

The undersigned signatories represent and warrant that they are authorized to execute this declaration on behalf of St. Francis Hospital and Medical Center and St. Francis Care Medical Group, P.C.

We declare under penalty of perjury that the foregoing is true and correct.

Executed on this 1<sup>st</sup> day of February 2005.

  
Christopher M. Dadlez  
President and Chief Executive Officer  
St. Francis Hospital and Medical Center

  
Susan L. Freeman, M.D.  
President  
St. Francis Care Medical Group, P.C.

**OVERPAYMENT REFUND****TO BE COMPLETED BY MEDICARE CONTRACTOR**

Date: \_\_\_\_\_  
 Contractor Deposit Control # \_\_\_\_\_ Date of Deposit: \_\_\_\_\_  
 Contractor Contact Name: \_\_\_\_\_ Phone # \_\_\_\_\_  
 Contractor Address: \_\_\_\_\_  
 Contractor Fax: \_\_\_\_\_

**TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER**

*Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.*

PROVIDER/PHYSICIAN/SUPPLIER NAME \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 PROVIDER/PHYSICIAN/SUPPLIER # \_\_\_\_\_ CHECK NUMBER # \_\_\_\_\_  
 CONTACT PERSON: \_\_\_\_\_ PHONE # \_\_\_\_\_ AMOUNT OF CHECK  
 \$ \_\_\_\_\_ CHECK DATE \_\_\_\_\_

**REFUND INFORMATION****For each Claim, provide the following:**

Patient Name \_\_\_\_\_ HIC # \_\_\_\_\_  
 Medicare Claim Number \_\_\_\_\_ Claim Amount Refunded \$ \_\_\_\_\_  
 Reason Code for Claim Adjustment: \_\_\_\_\_ (Select reason code from list below. Use one reason per claim)

*(Please list all claim numbers involved. Attach separate sheet, if necessary)*

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: \_\_\_\_\_*

**For Institutional Facilities Only:**

Cost Report Year(s) \_\_\_\_\_  
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

**For OIG Reporting Requirements:**

Do you have a Corporate Integrity Agreement with OIG? Yes No

**Reason Codes:**

<b><u>Billing/Clerical Error</u></b>	<b><u>MSP/Other Payer Involvement</u></b>	<b><u>Miscellaneous</u></b>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including	16 - Medical Necessity
05 - Modifier Added/Removed	Black Lung	17 - Other (Please Specify)
06 - Billed in Error	12 - Veterans Administration	
07 - Corrected CPT Code		